

United States Senate

WASHINGTON, DC 20510-0903

October 10, 2003

Mr. Amit Sachdev
Associate Commissioner Legislative Affairs
Food and Drug Administration
1555 Parklawn Building
5600 Fishers Lane
Rockville, Maryland 20857

Dear Mr. Sachdev:

Enclosed is a letter from Fred Kinnard.

I would appreciate your reviewing the information that has been presented and providing me with your comments. Please address your reply to my state office:

2252 Killearn Center Boulevard, Suite 300
Tallahassee, Florida 32309-3573
Attention: Ms. Pat Gris 
Telephone: 850-907-1100
Direct Line: 850-907-1109
Facsimile: 850-894-3222

Your cooperation and assistance are greatly appreciated. I look forward to hearing from you soon.

With kind regards,

Sincerely,



United States Senator

BG/pdg

Enclosure

03-5004

**Kinnard's[®]
Pharmacy****Sarasota's Original Compounding Pharmacy.**

September 30, 2003

Dr. Stephen F. Sundlof, Director
Center for Veterinary Medicine
U.S. Food and Drug Administration (HFV-1)
7500 Standish Place
Rockville, MD 20855

Dear Dr. Sundlof:

I am Fred Kinnard, R.Ph. and have owned Kinnard's Compounding Pharmacy in Sarasota since 1968. I have been compounding medication for household pets all of these years and feel that the discontinuance of bulk chemicals may cause severe hardship or death to many of these animals. I certainly understand that these chemicals should not be introduced into the food supply through farm animals.

I feel CVM issued this Compliance Policy Guide in final form without allowing opportunity for comments, in violation of FDA Good Guidance Practices. Many requirements of this CPG are extremely problematic and deserve a comment period before being put into effect. I also feel the FDA's prohibition in this CPG against compounding from bulk active pharmaceuticals is extremely problematic. It is essential that pharmacists be allowed to compound for non-food producing animals from bulk drug substances.

I would ask the FDA to withdraw the CPG and reissue it in draft form to allow for pharmacists, veterinarians, and patients to comment on its provisions before it is implemented. We need a working community standard that patients, professionals, and administrations can implement that is not detrimental to the patient and will provide improved efficacy for all involved.

Sincerely,

Fred A. Kinnard, R.Ph.
Compounding pharmacist (FL Lic#10873)
7654 Cove Terrace
Sarasota, FL 34231
Phone: 941-922-3428(H) 941-366-0880(W) 941-366-4977(Fax)
e-mail: mdlcomp@mindspring.com
cc: Mark McClellan, FDA Commissioner
cc: Senator Bob Graham
cc: Senator Bill Nelson
cc: Representative Katherine Harris
cc: IACP

*I wanted you to be aware
of this recent development*